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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/581,528	10/26/2000	Masatoshi Takeda	P19743	6685
7055	7590	04/19/2005	EXAMINER	
GREENBLUM & BERNSTEIN, P.L.C. 1950 ROLAND CLARKE PLACE RESTON, VA 20191			CROUCH, DEBORAH	
			ART UNIT	PAPER NUMBER
			1632	

DATE MAILED: 04/19/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/581,528	TAKEDA ET AL.	
	Examiner	Art Unit	
	Deborah Crouch, Ph.D.	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 January 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-11, 13 and 16-51 is/are pending in the application.
- 4a) Of the above claim(s) 3, 4, 10, 11, 18-32, 34, 35 and 43-50 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 2, 5-9, 13, 16, 17, 33, 36-42 and 51 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 07 July 2000 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>5/29/03</u> . | 6) <input type="checkbox"/> Other: _____ |

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Applicant's arguments filed January 27, 2005 have been fully considered but they are not persuasive. The amendment has been entered. Claims 1-11, 13 and 16-51 are pending. Claims 1, 2, 5-9, 13, 16, 17, 33 and 36-42 are subject to present examination. Claims 3, 4, 10, 11, 18-32, 34, 35 and 43-51 are withdrawn from consideration as to nonelected subject matter.

This application has been docketed to Deborah Crouch, Ph.D., AU 1632. Communications should be so addressed.

The rejection made in the office action mailed July 28, 2004 under 35 U.S.C. § 112, first paragraph, written description is withdrawn. The rejection made in the office action mailed July 28, 2004 under 35 U.S.C. § 112, second paragraph is withdrawn.

The amendment filed January 27, 2005 is objected to under 35 U.S.C. 132(a) because it introduces new matter into the disclosure. 35 U.S.C. 132(a) states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: The amendment changes certain amino acid representation. However, evidence has not been presented that the specification supports these changes to the disclosed amino acid sequences. As an example, the amendment states that "V" represents a base other than T. There is no indication of support for this change. Further, "V" is known in the art to be the letter representation for valine and only valine. This definition would be repugnant to the art at the time of filing. Applicant has not offered any explanation for the alterations nor have they offered any evidence that the specification or the priority document supports these amendments.

Applicant is required to cancel the new matter in the reply to this Office Action.

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The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 2, 5-9, 13, 16, 17, 33, 36-42 and 51 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claims contain subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention for reasons of record set forth in the previous office actions mailed November 8, 2002, July 30, 2003 and July 28, 2004.

In summary, the specification while teaches making of a knockin transgenic mouse with a OS2 mutation (isoleucine at position 213 changed to threonine or I213T), does not teach phenotypes or characteristics of the knockin mouse, and therefore an artisan of skill would not know how to use the transgenic mouse. Guo et al (Nature Medicine 5: 101-106, 1999) noted that a presenilin-I knockin mouse did not show any signs of an overt mutant phenotype indicating that the targeted M146 mutation does not impair normal development and physiological functions of presenilin-I, although the mouse did show signs of hypersensitivity to seizure-induced synaptic degeneration and necrotic neuronal death in the hippocampus, when the adult mouse was administered excitotoxin kainite (see the entire article). These articles result indicate that a presenilin-I knockin mouse will require treatment with an agent for its use, however, the specification as filed does not teach as to what were the phenotypes of the claimed knockin animals and in view of the observation by Guo et al and unpredictability of the art of transgenesis, an artisan would not know what

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will be the phenotype of any knockin animal encompassed by the claimed invention and therefore would not know how to them.

Applicant has not provided any arguments or evidence that this rejection is not correct.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Deborah Crouch, Ph.D. whose telephone number is 571-272-0727. The examiner can normally be reached on M-Th, 8:30 AM to 7:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla, Ph.D. can be reached on 571-272-0735. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Deborah Crouch, Ph.D.
Primary Examiner
Art Unit 1632

April 12, 2005